UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

	Case No. 1:08 GD 50000
	MDL No. 1909
IN RE: GADOLINIUM BASED CONTRAST AGENTS PRODUCTS LIABILITY LITIGATION	**Judge Dan Aaron Polster**

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Margaret Young
Plaintiff

v.

General Electric Company; GE Healthcare, Inc.; GE Healthcare Bio-Sciences Corp.;

Bayer Corporation; Bayer Healthcare Pharmaceuticals;

Tyco International Ltd.; Tyco Healthcare Ltd.; Tyco Holdings Ltd.; Tyco Healthcare Group LP; Mallinckrodt, Inc.; Covidian, Ltd.; and

Bracco Diagnostics, Inc.
Defendants

Case No. _____

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PLAINTIFF'S ORIGINAL COMPLAINT

COMES NOW, **MARGARET YOUNG**, Plaintiff, complaining of above named Defendants, Defendants herein, and for cause of action would respectfully show unto the Court as follows:

A. Jurisdiction

Plaintiff

1. The Plaintiff is a resident and citizen of Wake County in the state of North Carolina.

Defendants

2. The Defendants are as follows:

Defendant GE

a. Defendant General Electric Company is a New York corporation with its principal place of business at 3135 Easton Turnpike, Fairfield, Connecticut 06431.

b. Defendant GE Healthcare, Inc., is a Delaware corporation with its principal place of business at 101 Carnegie Center, Princeton, New Jersey.

c. Defendant GE Healthcare Bio-Sciences Corp. is a Delaware corporation with its principal place of business at 800 Centennial Avenue, Piscataway, New Jersey 08854.

d. Defendants GE Healthcare and GE Healthcare Bio-Sciences Corp. are subsidiaries or defendant General Electric Company, and the three are collectively referred to hereinafter as GE.

e. GE is the manufacturer and distributor of Ominscan, a contrast solution containing

gadolinium and used in magnetic resonance imaging (MRI) and magnetic resonance angiography

(MRA).

Defendant Bayer

f. Defendant Bayer Corporation is incorporated in a state other than North Carolina and has its headquarters in Robinson Township, Allegheny County, Pennsylvania, near Pittsburgh.

g. Defendant Bayer Healthcare Pharmaceuticals is incorporated in a state other than North Carolina and has its headquarters in Montville, New Jersey, and/or in Wayne, New Jersey.

h. Defendant Bayer Healthcare is a subsidiary of defendant Bayer Corporation, and they are jointly referred to hereinafter as Bayer.

i. Bayer is the manufacturer and distributor of Magnevist, Gadovist, and Vasovist contrast solutions containing gadolinium and used in magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA). Magnevist is approved for sale in the United States. Gadovist and Vasovist are not. References in this complaint to Bayer's contrast solution, or gadolinium containing contrast solution, are to Magnevist.

Defendant Tyco

j. Defendant Tyco International, Ltd., is incorporated in Bermuda and has its United States headquarters at. 9 Roszel Road, Princeton, New Jersey 08540.

k. Defendant Tyco Healthcare Ltd. is incorporated in Bermuda and has its United States headquarters at 15 Hampshire Street, Mansfield, Massachusetts 02048.

l. Defendant Tyco Holdings Ltd. is, or at least at one time was, incorporated in Bermuda and is a predecessor-in-interest to Tyco Healthcare Ltd., and if Tyco Holdings Ltd. still exists, it is incorporated, and has its United States headquarters, in a jurisdiction other than North Carolina.

m. Defendant Tyco Healthcare Group LP is, or at least was, an operating division of Tyco International Ltd and/or Tyco Healthcare, Ltd., that was formed, and has its United States headquarters, in a jurisdiction other than North Carolina.

n. Defendant Mallinckrodt, Inc., is incorporated in a jurisdiction other than North Carolina and has its headquarters in St. Louis, Missouri.

o. Defendant Covidian, Ltd., is a Bermuda corporation with its United States headquarters at 15 Hampshire Street, Mansfield, Massachusetts 02048. It became a successor-in-interest to Tyco Healthcare Ltd., and Tyco Healthcare Group LP as of

July 2, 2007.

p. Tyco Healthcare Ltd., Tyco Holdings Ltd., Tyco Healthcare Group LP, Covidan, Ltd., and Mallinckrodt, Inc., are subsidiaries, or otherwise operate under the corporate umbrella, of Tyco International Ltd., and all are referred to collectively as "Tyco" in the balance of this complaint.

q. Tyco is the manufacturer and distributor of OptiMARK (Gadoversetamide injection) contrast solution containing gadolinium and used in magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA).

Defendant Bracco

r. Defendant Bracco Diagnostics, Inc., is incorporated in a state other than North Carolina and has its headquarters at 107 College Road East, Princeton, New Jersey. It is referred to hereinafter as Bracco.

s. Bracco is the manufacturer and distributor of MultiHance and ProHance, contrast solutions containing gadolinium and used in magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA).

Identity of Parties

3. Many of the paragraphs herein apply only to specific Defendants. Those Defendants are clearly identified at the beginning of the paragraphs. Any paragraph that is not so identified applies to all the Defendants named herein.

4. "BAYER" DEFENDANTS: There exists, and at all times mentioned there existed, a unity of interest in ownership between BAYER CORPORATION and BAYER HEALTHCARE PHARMACEUTICALS,, such that any individuality and separateness between them has ceased and these Defendants are the alter-egos of one another and exerted control over each other. At all

times pertinent to this matter, they shared officers and directors and made all decisions in a uniform voice. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from one another will permit an abuse of the corporate privilege, would sanction fraud and promote injustice. Hereinafter, BAYER CORPORATION and BAYER HEALTHCARE PHARMACEUTICALS will be referred to collectively as "BAYER," unless otherwise specified.

5. "GE" DEFENDANTS: There exists, and at all times mentioned there existed, a unity of interest in ownership between GENERAL ELECTRIC COMPANY, GE HEALTHCARE, INC., and GE HEALTHCARE BIO-SCIENCES CORP., such that any individuality and separateness between them has ceased and these Defendants are the alter-egos of one another and exerted control over each other. At all times pertinent to this matter, they shared officers and directors and made all decisions in a uniform voice. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from one another will permit an abuse of the corporate privilege, would sanction fraud and promote injustice. Hereinafter, GENERAL ELECTRIC COMPANY, GE HEALTHCARE, INC., and GE HEALTHCARE BIO-SCIENCES CORP. will be referred to collectively as "GE," unless otherwise specified.

6. "TYCO" DEFENDANTS: There exists, and at all times mentioned there existed, a unity of interest in ownership between TYCO INTERNATIONAL LTD., TYCO HEALTHCARE LTD., TYCO HOLDINGS LTD., TYCO HEALTHCARE GROUP LP, MALLINCKRODT, INC., and COVIDIAN LTD., such that any individuality and separateness between them has ceased and these Defendants are the alter-egos of one another and exerted control over each other. At all times pertinent to this matter, they shared officers and directors and made all decisions in a uniform voice. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from one another will permit an abuse of the corporate privilege, would sanction fraud and promote injustice. Hereinafter, TYCO INTERNATIONAL LTD., TYCO HEALTHCARE LTD., TYCO

HOLDINGS LTD., TYCO HEALTHCARE GROUP LP, MALLINCKRODT, INC., and COVIDIAN LTD. will be referred to collectively as "TYCO," unless otherwise specified.

7. As employers, masters, principals, and/or control persons of unnamed sales representatives of gadolinium contrast agents, Defendants knew or reasonably should have known of their acts and omissions and failed to properly supervise him/her and/or to insure his/her compliance with applicable regulations, and/or to insure that the sales representatives' acts or responsibilities were properly and adequately performed. Plaintiff asserts that the Defendants employed the unnamed sales representatives, authorized the doing and manner of their acts, and/or ratified or approved their acts. Plaintiff further alleges that the unnamed sales representatives were employed by the Defendants in a managerial capacity, as that phrase is understood at law, and that their actions or omissions were done within the scope of their employment. Additionally or in the alternative, if same be necessary, Plaintiff asserts that the unnamed sales representatives were agents or ostensible agents of Defendants, acting with actual or apparent authority, and that Plaintiff's prescriber's reliance on this authority was justified and reasonable. Thus, Plaintiff asserts that the Defendants are subject to liability for the action of all unnamed sales representatives.

Amount in controversy

8. The amount in controversy exceeds $75,000.00, exclusive of interest and costs.

B. Venue

9. Pursuant to Pretrial Order No. 1 of Judge Dan Aaron Polster of the Northern District of Ohio, MDL 1909, notwithstanding the provisions of Case Management Order No. 3, paragraph 3, Defendants will not challenge the venue of any action filed directly in the Northern District of Ohio for purposes of pretrial proceedings. Upon the completion of all pretrial proceedings applicable to a

case directly filed before this Court pursuant to this Order, this Court, pursuant to 28 U.S.C. § 1404(a), will transfer that case to a federal district court of proper venue, as defined in 28 U.S.C. § 1391, based on the recommendations of the parties to that case.

10. The defendants do, and at all times mentioned in this complaint did, business in North Carolina through the sale of the contrast solutions identified above to various medical providers.

11. The defendants do, and at all times mentioned in this complaint did, business in North Carolina through the sale of various healthcare products other than contrast solutions to institutions, distributors, and individuals in the state.

Doing business in Wake County

12. The defendants do, and at all times mentioned in this complaint did, business in this district and division through the sale of the contrast solutions identified above to various medical providers in the county.

13. The defendants do, and at all times mentioned in this complaint did, business in this district and division, through the sale of various healthcare products other than contrast solutions to institutions, distributors, and individuals in this district and division.

Tortious injury in Wake County

14. This complaint alleges that the defendants caused tortuous injury to the plaintiff in this district and division, through administration of the defendants' gadolinium-containing contrast solution in this district and division.

15. All conditions precedent have occurred.

C. Nephrogenic Systemic Fibrosis

16. Nephrogenic Systemic Fibrosis, also known as Nephrogenic Fibrosing Dermopathy and referred to hereinafter as NSF, is predominantly characterized by discoloration, thickening, tightening, and swelling of the skin.

17. NSF is caused by gadolinium used in contrast solutions used in enhanced Magnetic Resonance Imaging ("MRI") and Magnetic Resonance Angiography ("MRA"). In those who will develop NSF, symptoms can begin days-to-months after injection of contrast solution containing gadolinium. Published literature puts the reported time period for symptoms to appear from as short as two days to as long as fourteen months.

18. Fibrotic and edematous changes caused by NSF produce muscular weakness and inhibit flexion and extension of joints, resulting in contractures. NSF can progress to the point where a person effectively loses use of arms, legs, hands, and/or feet.

19. NSF Skin changes frequently begin as darkened patches or plaques and progress to a "woody" texture and are accompanied by burning, itching, and/or severe pain in the areas of involvement.

20. NSF can cause fibrosis and scarring of lungs, heart, liver, and muscles and can be fatal. It is a progressive disease with no known cure and no consistently effective treatment.

21. The symptoms of NSF were observed and discussed in scientific literature years before the condition was given a name or the cause was understood. The NSF and/or NFD terminology has been used for about ten years. Before that, the condition was referred to as scleromyxedema, scleroderma, or some other connective tissue disease.

22. NSF has been reported thus far only in people whose kidney function was compromised at the time of injection with gadolinium-containing contrast solution.

23. NSF did not exist until gadolinium-containing contrast solutions came into use

for enhancing MRI and MRA scans.

D. Harm to the plaintiff

24. In August 2002, December 2004 and January 2006, Plaintiff, had enhanced MRIs in North Carolina.

25. The defendants' gadolinium-containing contrast solution identified above (and hereinafter referred to as "contrast solution") was used for the MRI.

26. The plaintiff was in kidney failure when and before the MRI identified in paragraph 24 above was performed.

27. The plaintiff began to exhibit symptoms and conditions consistent with NSF within days after the MRI identified in paragraph 24 was performed.

28. The plaintiff was diagnosed with NSF on January 3, 2005. Prior to her MRIs, the plaintiff did not know, and had no reason to believe, that his NSF had been caused by the gadolinium contrast injection.

29. As results of NSF, Plaintiff:

a. has impaired use of her hands that is becoming progressively worse,

b. is on daily pain medications,

c. has disfigured skin and joints;

d. is in jeopardy of having her heart and lungs impaired;

e. is unable to work regularly and has sustained past and future income loss because of this; and

f. has incurred, is incurring, and will incur in the future, medical expenses for treatment of NSF.

30. The defendants' conduct and contrast solution, under any one or more of the bases for recovery alleged in this complaint, are contributing, substantial contributing, legal, and/or proximate causes of the plaintiff's NSF and its consequences as identified above.

E. Tolling of Limitations: Discovery Rule and/or Fraudulent Concealment/Equitable Estoppel

31. The nature of Plaintiff's injuries and the relationship of those injuries to the use of Gadolinium contrast agents, was inherently undiscoverable and/or was concealed by the medical provider administering the agent. Additionally or in the alternative, Plaintiff's claims against Defendants were inherently undiscoverable and/or concealed by the actions of the companies. Consequently, the discovery rule and/or doctrine of fraudulent concealment should be applied to toll the running of the statute of limitations until Plaintiff knew and understood or through reasonable care and diligence, should have known of the existence of and understood the nature of Plaintiff's claims against Defendants. Plaintiff did not discover or understand the nature of, and through the exercise of reasonable care and due diligence, could not have discovered or understood the nature of the injuries or their relationship to use of any gadolinium contrast agents until within, at most, two years of the filing of this suit. Further, prior to that time, Plaintiff did not have knowledge of facts that would lead a reasonable prudent person to make inquiry to discover the Defendants' tortuous conduct.

F. First basis for imposing liability for compensatory damages: Strict Liability in Tort

32. One or more of the defendants developed, patented, manufactured, distributed, and marketed the contrast solution.

33. The contrast solution was not materially altered between the time it was placed into the stream of commerce by the defendants and the time it was administered to the plaintiff.

34. The contrast solution was unreasonably dangerous, not reasonably safe, and/or did not meet reasonable consumer expectations, because of:

a. design defects,

b. use defects (inadequate warnings), and/or

c. defects attributable to inadequate testing.

35. As a direct and proximate result of defendants' conduct, plaintiff suffered the injuries and damages specified herein.

G. Second basis for imposing liability for compensatory damages: Negligence

36. Defendant introduced its gadolinium contrast agents described herein into the stream of commerce.

37. At all material times, defendant had a duty to plaintiff and other consumers of their products to exercise reasonable care in order to properly design, manufacture, produce, test, study, inspect, mix, label, market, advertise, sell, promote, and distribute these products. This includes a duty to warn of side effects, and to warn of the risks, dangers, and adverse events associated with their contrast agents, which would also warn plaintiff's physicians of these factors.

38. Defendants knew, or in the exercise of reasonable care should have known, that its contrast agents were of such a nature that it was not properly designed, manufactured, produced, tested, studied, inspected, mixed, labeled, marketed, advertised, sold, promoted, and distributed, and it was likely to cause injury to those who ingested them.

39. Defendants were negligent in the design, manufacture, production, testing, study, inspection, mixture, labeling, marketing, advertising, sales, promotion, and distribution of its contrast agents, and breached duties it owed as set forth herein. In particular, defendant:

a. Failed to use due care in the preparation of their contrast agents to prevent the aforementioned risks to patients with kidney problems when the drugs were ingested;

b. Failed to use due care in the design of their contrast agents to prevent the aforementioned risks to patients with kidney problems when the drugs were ingested;

c. Failed to conduct adequate pre-clinical testing and research to determine the safety of their contrast agents;

d. Failed to conduct adequate post-marketing surveillance to determine the safety of their contrast agents;

e. Failed to accompany their products with proper warnings regarding all possible adverse side effects associated with the use of their contrast agents and the comparative severity and duration of such adverse effects;

f. Failed to use due care in the development of their contrast agents to prevent the aforementioned risks to individuals when the drugs were ingested;

g. Failed to use due care in the manufacture of their contrast agents to prevent the aforementioned risks to individuals when the drugs were ingested;

h. Failed to use due care in the inspection of their contrast agents to prevent the aforementioned risks to individuals when the drugs were ingested;

i. Failed to use due care in the labeling of their contrast agents to prevent the aforementioned risks to individuals when the drugs were ingested;

j. Failed to use due care in the marketing of their contrast agents to prevent the aforementioned risks to individuals when the drugs were ingested;

k. Failed to use due care in the promotion of their contrast agents to prevent the aforementioned risks to individuals when the drugs were ingested;

l. Failed to use due care in the selling of their contrast agents to prevent the aforementioned risks to individuals when the drugs were ingested;

m. Failed to provide adequate information to healthcare providers for the appropriate use of their contrast agents;

n. Failed to adequately warn about the health consequences, risks, and adverse events caused by their contrast agents; and

o. Were otherwise careless and negligent.

40. Defendant knew or should have known that their contrast agents caused unreasonable harm and dangerous side effects that many users would be unable to remedy by any means. Despite this, Defendants continued to promote and market their contrast agents for use by consumers, including Plaintiff, when safer and more effective methods of countering the negative health effects were available.

41. It was foreseeable to defendants that consumers, including plaintiff, would suffer injury as a result of defendant's failure to exercise ordinary care as described herein.

42. As a direct and proximate result of defendant's conduct, plaintiff suffered the injuries and damages specified herein.

H. Third basis for imposing liability for compensatory damages: Breach of Implied Warranty

43. A warranty that a product is reasonably fit for its intended purpose is imposed by law on the seller of the product, including the defendants as sellers of the contrast solution.

44. Plaintiff and/or Plaintiff's healthcare provider(s) reasonably relied on the belief that the contrast solution would be reasonably fit for its intended purpose.

45. One or more of the defendants breached this implied warranty, because the contrast solution was not reasonably fit for its intended purpose.

46. As a direct and proximate result of defendant's conduct, plaintiff suffered the injuries and damages specified herein.

I. Fourth basis for imposing liability for compensatory damages: Breach of Express Warranty

47. One or more of the defendants expressly warranted that the contrast solution administered to Plaintiff would be reasonably fit for its intended purpose.

48. Plaintiff and/or Plaintiff's healthcare provider(s) reasonably relied on the belief that the contrast solution would be reasonably fit for its intended purpose.

49. One or more of the defendants breached this express warranty, because the contrast was not reasonably fit for its intended purpose.

50. As a direct and proximate result of defendant's conduct, plaintiff suffered the injuries and damages specified herein.

J. Basis for Allowing Punitive Damages: Deliberate, Intentional, Reckless and/or Malicious Conduct

51. The totality of the defendants' conduct, as described in this complaint and by clear and convincing evidence, is susceptible of being interpreted by reasonable people as demonstrating an irresponsible attitude toward the safety and health of those who would receive its contrast solution, including the plaintiff, which was deliberate, willful, intentional, reckless, and/or malicious

K. Causation

52. Each of the aforementioned acts, omissions, breaches of warranty, and/or defective products of Defendants was a proximate and/or a producing cause of the injuries to Plaintiff.

L. Damages – In General

53. Plaintiff was injured as a direct and proximate result of the actions of Defendants and of the ingestion by Plaintiff of Defendants' contrast agent. Such injuries were the direct result of the aforementioned acts, omissions, breaches of warranty and/or defective products of Defendants. As a result, Plaintiffs claim the following damages in this suit:

a. injuries, pain and suffering, disability, mental anguish and other losses sustained by Plaintiff, compensatory damages and non-economic damages in excess of $75,000;

b. punitive damages;

c. attorney fees, expenses and costs of this action;

d. prejudgment interest; and

e. such further relief as this Court deems necessary, just, and proper.

M. Prayer

WHEREFORE, PREMISES CONSIDERED, Plaintiff prays that Defendants be cited to appear and answer herein; that upon final trial hereof, Plaintiff recover her damages as specified

above from the Defendants, both jointly and severally, plus punitive damages, costs of court and pre-judgment and post-judgment interest at the legal rate in an amount to be determined by a jury of no more than $100,000,000.00 dollars; and that Plaintiff have such other and further relief, general and special, at law and in equity, to which he may be justly entitled under the facts and circumstances.

N. A jury trial is requested

Plaintiff hereby requests a trial by jury.

Respectfully submitted,

MATTHEWS & ASSOCIATES

By: _____

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